Quigley 12/13/99 ph
HFI-35 M3242

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive Suite 400
New Orleans, LA. 70127

Telephone (504) 253-4500
FAX (504) 253-4566

December 9, 1999

WARNING LETTER NO. 2000-NOL-08

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Ronald J. Noel, Owner and President
Atchafalaya Crawfish Processors, Inc.
1702-B Grand Anse Highway
Breaux Bridge, Louisiana 70517

Dear Mr. Noel:

Between April 27 and April 29, 1999, an investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your crawfish processing facility, located at Atchafalaya Crawfish Processors, Inc., 1509 Henderson Hwy, Henderson, Louisiana. The investigator documented that your firm was not in compliance with FDA's seafood processing regulations and the Good Manufacturing Practices requirements for foods. This causes your finished product, cooked crawfish tail meat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, in that you failed to operate in accordance with the requirements of Title 21, *Code of Federal Regulations* (CFR), Part 123, and the Current Good Manufacturing Practice (CGMP) regulations for foods, Title 21, CFR, Part 110.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Points (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" (CCP) in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the April 1999 inspection, of your crawfish processing firm, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the March 23-24, 1998, inspection and stated in the untitled letter sent to your firm on July 17, 1998. The subsequent inspection on April 27-29, 1999, revealed similar deficiencies. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the Form FDA 483, which presents her evaluation of your firm's performance regarding

various aspects of the HACCP and CGMP requirements. The observations of concern to us are as follows:

- You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with Title 21, CFR, Part 123.6(c)(7). However, you did not have monitoring records to document the time and temperature at the cook step critical control point to control pathogen survival in ten batches of crawfish processed on April 27, 1999;

- You must take appropriate corrective action when a deviation from a critical limit occurs, in order to comply with Title 21, CFR, Part 123.7(a). However, your firm did not take an appropriate corrective action to control pathogen growth when your process for 20 of 42 batches of crawfish deviated from your critical limit during the period April 14-27, 1999, at the ice slush critical control point. Further, your firm did not take an appropriate corrective action to control pathogen growth after a batch of crawfish cooked on April 27, 1999, did not reach the critical temperature during the cook step;

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with Title 21, CFR, Parts 123.6(b) and (c)(1). However, your firm's HACCP plan for crawfish does not list the food safety hazard of *Clostridium botulinum* toxin formation. While freezing vacuum packaged crawfish tailmeat is an appropriate control for the hazard of *C. botulinum* growth and toxin formation, the words "keep frozen, thaw under refrigeration immediately before use" or " keep frozen, break seal before thaw" are needed to ensure the safety of the product. The HACCP plans should list the *C. botulinum* for vacuum packaged product with freezing as the control. The critical limit is "labeling with the appropriate wording";

- You failed to monitor the critical control limit for the processing steps, hand washing, weighing and packing, as required by Title 21, CFR, Part 123.6(b); and,

- You must have a HACCP plan that lists monitoring procedures to comply with Title 21, CFR, Parts 123.6(c)(4) and (6). However your HACCP plan for crawfish does not list the monitoring procedures that indicate the product achieves an internal temperature of 180° F.

Objectionable conditions listed on the Form FDA-483 and Form 3501 are an indication that sanitation monitoring [Title 21, CFR, Part 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions include the following:

- Boiling employee routinely stored gloves on mesh sacks, which previously contacted live crawfish and then contacted cooked crawfish and baskets containing cooked crawfish, and the baskets were not washed or sanitized;

- On two occasions the thermometer probe contacted live crawfish, and was then inserted into cooked crawfish without being washed and sanitized; and,

- Peeling room employees did not wash and sanitize their hands after returning from outside the processing area, and prior to peeling cooked crawfish, employees handled stools and continued to peel cooked crawfish without washing and sanitizing their hands, and employees wore jewelry while they peeled cooked crawfish.

It is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should by directed to Patricia K. Schafer, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127, telephone number (504) 253-4500. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Schafer.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA 483